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(54) Removable endo-arterial devices intended to repair detachments in arterial walls.

(57) The invention covers removable endo-arterial devices intended to repair detachments in the arterial walls.

A device according to said invention includes a deformable cuff (3) made of a netting of interlocked wires and fixed to the distal end of a catheter (4) the other end of which is equipped with a funnel (4a). It also includes a stiff wire (7) extending over the entire length of the catheter and attached to the distal end of said deformable cuff (3). When this wire is pulled, the cuff is dilated and applies itself against the arterial wall.

One application is the repair of flaps of arterial wall which were detached during the course of an intervention correcting a stenosis with an inflatable balloon.

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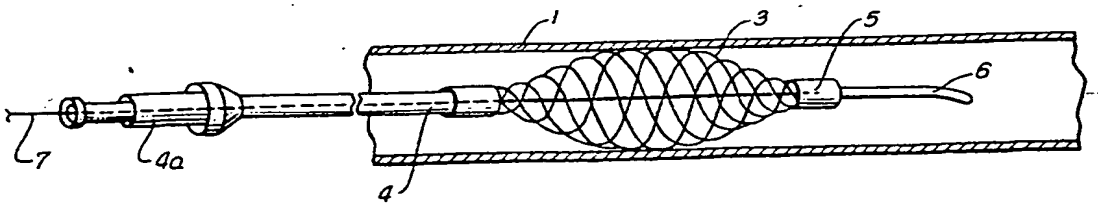
FIG. 2



REMOVABLE ENDO-ARTERIAL DEVICES INTENDED TO REPAIR DETACHMENTS IN ARTERIAL WALLS

Technical Field

The present invention provides endo-arterial devices temporarily installed in an artery in order to re-attach flaps which have been detached from the wall.

The technical field of the invention is the construction of surgical equipment used in cardio-vascular interventions.

Background of the Invention

There are known devices consisting of a small inflatable balloon at the end of a catheter used to dilate strictures in the arteries, especially the coronary arteries.

Such a catheter bearing a balloon is introduced into an artery, for example into the femoral artery, until the balloon reaches the stricture. The balloon is then inflated with a fluid pumped in through the catheter and pushes back the arterial wall, thus eliminating the stricture. The balloon must then be deflated very quickly, since it blocks the artery and impairs blood circulation.

It so happens that a similar intervention may cause detachments of the part of the arterial wall called intima, and the detached wall flaps inhibit the blood circulation and may result in severe medical complications and even be fatal if circulation is interrupted.

Devices consisting of a cylindrical elastic cuff inserted over an inflatable balloon fixed to the end of a catheter have been tried for the prevention of such accidents. The balloon is folded back over the cuff so as to keep the latter in an elongated shape of small diameter while it is being pushed through the arteries. Once the balloon bearing the elastic cuff has arrived at the site of the wall detachment, it is inflated so that the folded part slips loose releasing the cuff which increases in diameter and plasters itself against the internal wall of the artery where it remains indefinitely. This device not only has the inconvenience of introducing a foreign body into the artery to remains stationary there, but also presents risks of blood clots to the patient.

Brief Summary of the Invention

The present invention provides a device consisting of a deformable cuff made up of a net of twisted and interlocking wires mounted at the end of a catheter which is then introduced into an artery. It also includes means activated from the external end of the catheter to move the two ends of the deformable cuff closer together or farther apart in order to give the cuff a wider shape which presses it against the arterial wall or a flat, elongated shape which permits introduction of the cuff and catheter into the artery or their withdrawal.

According to a preferred embodiment of the invention, the means used to reduce or extend the distance between the two ends of the deformable cuff are made up by a wire of the piano wire type which makes it possible to exert a push and which is fixed to the distal end of the cuff while freely passing through the proximal end of it and extending through the entire length of the catheter.

According to another embodiment, a device according to the present invention includes, in addition, an inflatable balloon located inside the deformable cuff and is mounted at the end of an inflation tube which, in turn, runs inside the catheter.

The invention provides new devices usable in cardio-vascular interventions, especially in interventions intended to remove stenoses of the coronary arteries in case of a severe risk of infarct or after an infarct has occurred.

Devices according to the present invention have the advantage that the deformable net allows the blood to pass between its mesh openings when it is applied against the wall of an artery. It can therefore be left in place for a duration on the order of one or more hours, which is more than sufficient to ensure cicatrization of the flaps detached from the arterial wall.

As compared to the known devices which involve an elastic cuff remaining stationary in the artery, devices according to the present invention have the advantage of being removable so that there is no risk of rejection phenomena or of the formation of blood clots. The devices according to the present invention include an inflatable balloon placed inside a cuff or deformable net, making it possible to treat a stenosis and, if necessary, to immediately repair the arterial wall. They therefore reduce the risk of postoperative complications and can even be used for interventions on strictures of the common trunk of the coronary arteries.

Description of the Drawings

The following detailed description refers to the enclosed drawings which represent examples of embodiments of the devices according to the present invention without being in any way limitative.

Fig. 1 is a longitudinal section of a first embodiment of a device according to this invention, in an elongated position.

Fig. 2 is a longitudinal section of a device according to Fig. 1 in the deployed position.

Fig. 3 is a longitudinal section of the fixation of the proximal end of the deformable cuff over the distal end of a catheter.

Fig. 4 is a longitudinal section of a second embodiment of a device according to this invention.

Fig. 5 is a longitudinal section of a third embodiment of a device according to this invention.

Fig. 6 is a cross section along VI-VI in Fig. 5.

Detailed Description

Fig. 1 shows a longitudinal section of an artery 1 which can be a coronary artery presenting a stricture or stenosis. During a first intervention, a catheter bearing an inflatable balloon at the end, was inserted into the artery until its balloon reached the stenosis. The balloon was then inflated with a fluid pumped in through the catheter. The inflated balloon pushed the arterial wall back and removed the stenosis. Since an inflated balloon blocks the artery, it had to be quickly deflated.

The inflating and deflating operation of the balloon may have been repeated several times. Subsequently, the balloon and catheter were withdrawn. During these operations, the internal wall of the artery, called intima, suffered some detachments 2 which, if not repaired, could block the artery and result in the death of the patient.

A device according to the present invention is depicted in the Figures and it can be advantageously used to facilitate repair of the detachments 2. It includes a removable endo-arterial prothesis intended to reduce the risks caused by the detachments 2 by applying the detached flaps of wall against the artery long enough for cicatrization to take place.

Fig. 1 shows a device according to this invention in its elongated shape which makes it possible to introduce or withdraw it from the artery.

Fig. 2 represents a device according to the invention in its deployed form in which it is widened so that it presses the detached wall flaps against the artery.

A device according to the invention includes a deformable cuff 3 made of a net of twisted and interlocked wires which could, for instance, be of stainless steel wires or of any other material having equivalent properties of compatibility with the blood. The deformable cuff 3 is fixed to the end of a small flexible tube 4 which has a diameter on the order of a few millimeters and serves as catheter. The distal end of the deformable cuff 3 is fixed to a small muff 5 on which a small flexible axial rod 6 is mounted which precedes the deformable cuff 3 and serves as guide for the latter along the artery.

A device according to Figs. 1 and 2 includes, in addition, an axial wire 7 of the piano-wire type which is fixed to the distal end of cuff 3, passes through the latter and extends the entire length of the catheter 4.

The catheter is preferably equipped at its proximate end with a funnel 4a of a known kind, for example, a funnel of the "LUER-LOCK" type. Wire 7 passes through the connection 4a, so that its end is accessible outside the catheter.

The practical application of a device according to Figs. 1 and 2 is the following:

The catheter bearing at its end a deformable cuff 3 which is fully elongated as shown in Fig. 1 and which therefore has a very small cross section is introduced into the artery. The progress of cuff 3 is controlled by radiography. When it reaches the area of the former stenosis, the end of wire 7 is pulled while the catheter is held in place in the artery. The pull exerted on the wire has the effect of bringing the distal end of cuff 3 close to its proximal end.

The cuff dilates as shown in Fig. 2 and comes to rest against the arterial wall, thus pressing the detached flaps back against the wall. Cuff 3 is left in this position for as long as one or more hours, since the blood can freely circulate through the mesh openings of the cuff which, at that time, are open. When it is deemed that sufficient time has elapsed for the flaps to adhere again to the wall, the outer end of wire 7, which is stiff enough not to bend, is pushed, thereby causing the distal end 5 of cuff 3 to move away, so that the cuff is again in its elongated position. The catheter 4, wire 7 and cuff 3 are then withdrawn together from the artery.

Fig. 3 is a larger scale axial section view of the proximal end of the deformable cuff 3. In this Figure the flexible tube or catheter 4 and the axial wire 7 are clearly seen.

Wires 8 which make up the end of the deformable cuff 3 are unraveled, inserted and fixed parallel to the axis between the end of tube 4 and a second tube 9 which is placed inside the latter and in which wire 7 runs freely. Tube 9 should preferably extend over the entire length of tube 4. The ends of wires 8 are glued between tube 4 and tube 9. A thermo-shrinkable sleeve 10 is preferably slipped over the proximal end of the cuff and then heat-shrunk to it.

In Fig. 3 it can be seen that the proximal end of the deformable cuff 3, which is fixed to catheter 4 and to the internal tube 9, slides freely over pull

wire 71.

Fig. 4 shows another embodiment of a device according to the invention.

When an inflatable balloon is introduced into an artery to correct a stenosis, the intervention generally begins with insertion into the artery of a guide wire of piano-wire type. The catheter is then slipped over this wire bearing at its end the inflatable balloon through which passes a small axial tube which engages the wire and follows it.

When the stenosis has been eliminated, the balloon is deflated and withdrawn from the artery, but the guide wire may be left in place for some minutes in case it becomes necessary to use the balloon again.

The device according to Fig. 4 is designed to be used in this case.

The numeral 11 represents a guide wire inserted into artery 1.

The device again includes a net 3 in form of a deformable cuff composed of interlocked wire mounted at the end of a small tube 4 and an axial wire 7 fixed to the distal end of the net which makes it possible to bring the latter closer to the proximal end in order to open the net or to push it farther away in order to close the latter. The distal end is located to the left in Fig. 4.

The device according to Fig. 4 also includes a small piece of tubing 12 which provides an axial opening or conduit 12a passing through the distal end of the cuff.

During application of the device according to Fig. 4, the end of the guide wire 11 which extends outside the artery and the patient is inserted through conduit 12a and then is passed through the mesh of the net so that it lies along the outside of tube 4. This permits the cuff to be guided on guide wire 11 until it reaches the zone where the stenosis had been located and previously corrected with an inflatable balloon.

During this insertion, the net 3 is in an elongated position. Once the device has arrived at the site, the axial wire 7 is pulled to open the net 3 and bring it into the position shown in Fig. 4. It may be left in this position for several hours. Subsequently, the net is re-folded by pushing on the axial wire 7 and pulling on tube 4, and the catheter is withdrawn from the artery along guide wire 11.

Figs. 5 and 6 represent another embodiment of a device according to the invention, including a netted cuff combined with an inflatable balloon.

To this date, inflatable balloons are used to correct the stenoses of the coronary arteries but only downstream from the common trunk, i.e. from the bifurcation of the circumflex and interventricular anterior arteries. They are used only very exceptionally to intervene on the common trunk because of the fact that detachments of the wall in the common trunk occurring after the intervention with an inflatable balloon would deprive a large part of the heart of irrigation and thus cause almost instantaneous death.

Figs. 5 and 6 show a device according to this invention which would permit interventions on stenoses of the common trunk and also on strictures located below the latter or in other arteries.

The device according to Fig. 5 includes a deformable balloon 13 of the kind currently used for angioplasty mounted at the end of a flexible tube 14. An axial tube 15 passes through the balloon from one end to the other and is fixed to the latter by one or both of its ends.

Figs. 5 and 6 show an embodiment having two coaxial tubes 14 and 15. As a variation, a single tube divided into two conduits by an inner partition could alternatively be used.

Tubes 14 and 15 extend to the outside where they preferably end in a funnel of a known type, for example a "LUER-LOCK" funnel, which may be simple or include a derivation for the injection of fluid into the catheter. The axial tube 15 is adapted to receive the guide wire 11 which has previously been introduced into the artery. The interspace between tubes 14 and 15 is intended for injection or pumping of the inflation fluid into balloon 13.

The device also includes a net 3 in form of a cuff, compromising plaited wires surrounding the inflatable balloon, the distal end of which is fixed to the distal end of the balloon, while the proximal end slides freely on tube 14.

For the sake of clarity in the drawing, net 3 is shown partly cut away in Fig. 5. Net 3 is mounted at its proximal end to a flexible tube 16 which encloses tubes 14 and 15.

The steps of practical application are the following:

When a stenosis is to be corrected, a guide wire 11 is first introduced into the artery. The axial tube 15 is then inserted over it and the device according to Fig. 5 is then pushed along guidewire 11 in a stretched configuration, i.e. the balloon 13 is collapsed and net 3 is elongated. The progress is checked by radiography. Once the net and balloon are in place, fluid is pumped in between tubes 14 and 15 which inflates the balloon and, in turn, dilates the artery and eliminates the stricture.

The highly flexible and deformable net 3 does not hamper the inflation of the balloon, since it slides in relation to the latter. The inflation of the balloon causes the dilation of the net.

Once the stricture has been eliminated, the fluid is withdrawn and the balloon is deflated, but the net remains in place against the internal wall of the artery. If necessary, the net is pressed against the wall of the artery by pushing on tube 16 which is sufficiently rigid to transmit the thrust. The axial

tube 15 is held fast to immobilize the distal end.

The blood circulates through the mesh of the netting and the prothesis may be left in this position for a time on the order of one to several hours which is more than enough for the eventual detachments of the inner arterial wall to heal.

Subsequently, tube 16 is pulled while keeping the axial tube 15 in place which has the effect of moving the two ends of net 3 further apart and putting the latter back into an elongated position, then the entire complex of the device is pulled out of the artery along guide wire 11.

In the embodiment according to Figs. 5 and 6, it is not necessary to use a wire to cause the deformation of cuff 3. The central tube 15 which is fixed to the distal end of the net and tube 16 which is fixed to the proximal end of the net are sufficient to permit moving these two ends toward or away from each other.

Claims

1. A removable endo-arterial device for repairing detachments of an arterial wall, comprising a deformable cuff (3) made of a netting of plaited and interlocked wires which is mounted at the end of a catheter (4, 16) and introduced into an artery (1) and which also includes means (7, 16) activated from the external end of said catheter (4) to bring two ends of said deformable cuff (3) closer together or move them farther apart in order to give it a wider shape which applies said cuff against the arterial wall or an elongated shape which permits said cuff and the catheter to be introduced into the artery or withdraw them from the latter.

2. The device according to claim 1, wherein said means to bring the two ends of said deformable cuff closer together or space them farther apart comprise a wire (7) of the piano-wire type, which is fixed to a distal end of said cuff while freely running through a proximal end of said cuff and extending through the entire length of the catheter.

3. The device according to either of claims 1 and 2, further including a piece of flexible guide rod (6) attached to the distal end of said deformable cuff.

4. The device according to either of claims 1 and 2, further including a guide tube (12) defining an axial conduit in the distal end of said deformable cuff, said guide tube being adapted to receive a guide wire (11) inserted into the artery and which returns through mesh openings in the netting.

5. The device according to claim 1, further including an inflatable balloon (13) mounted inside said deformable cuff at the end of an inflation tube (14) which runs inside a catheter (16) carrying said deformable cuff (3).

6. The device according to claim 5, further including an axial guide tube (15) which passes through said balloon, is fixed to the distal end of the latter and extends over the entire length of said catheter (16).

7. The device according to claim 6, wherein the distal ends of said balloon and said deformable cuff are fixed while the proximal end of said deformable cuff slides freely on said inflation tube (14).

Fig. 1

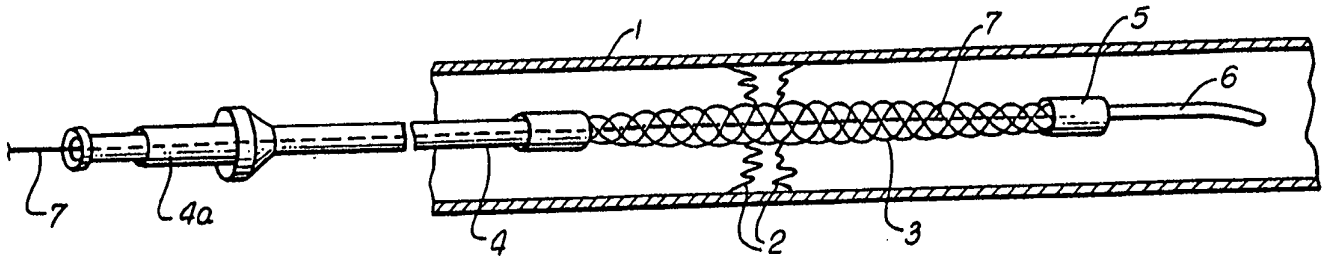


Fig. 2

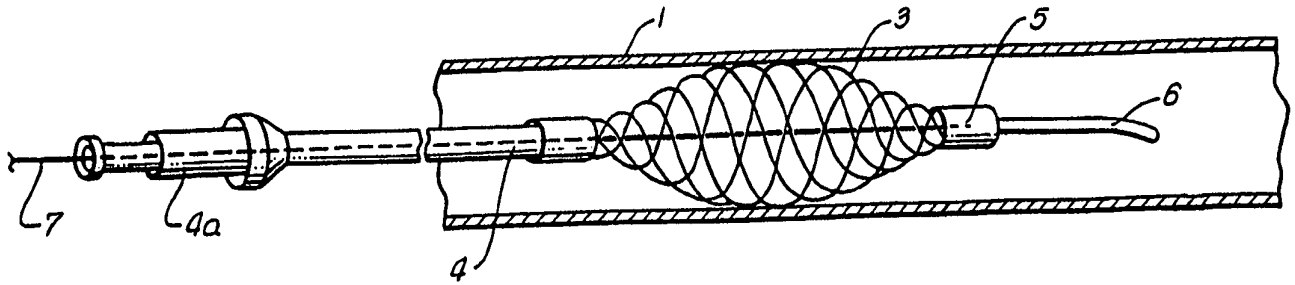


Fig. 3

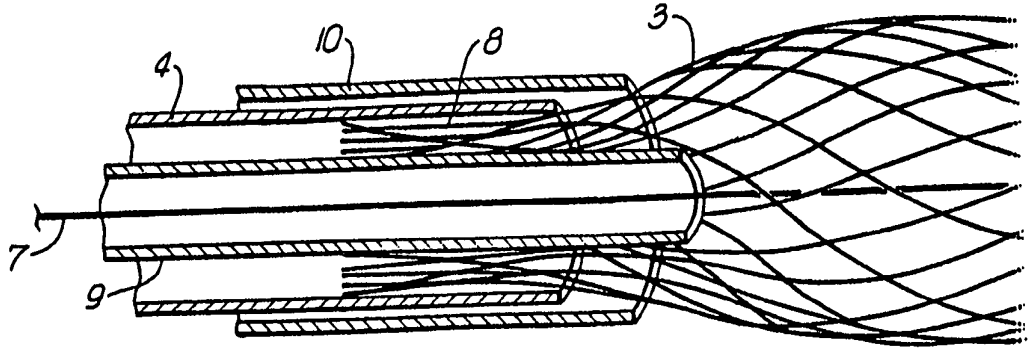


FIG. 4

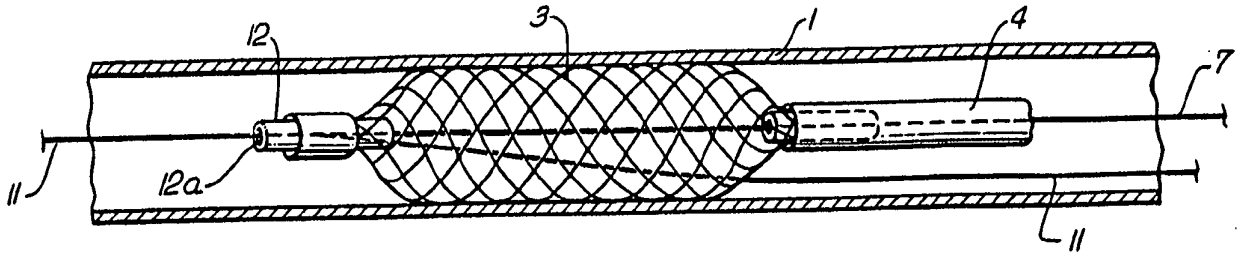


FIG. 5

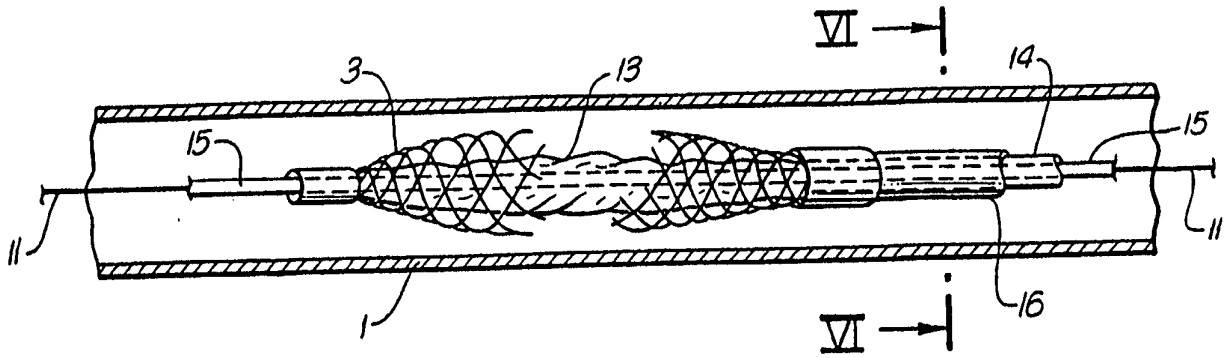
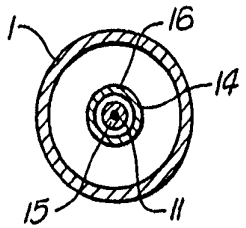


FIG. 6



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EUROPEAN SEARCH REPORT

Application Number

EP 88 12 1260

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Y	US-A-4 650 466 (LUTHER) * Column 2, lines 44-61; figures *	1-4	A 61 F 2/06 A 61 M 29/00
Y	US-A-1 677 671 (COUNCILL) * Page 1, line 103 - page 2, line 20; figures *	1-4	
Y	FR-A-2 454 293 (MEYER) * Page 1, lines 16-22; figure 3 *	4	
A	DE-A-3 532 653 (KALTENBACH) * Column 2, lines 25-29 *	1	
A	EP-A-0 183 372 (CAPONIGRO) * Page 10, lines 15-21; figures 3,4 *	1,5	
P,A	EP-A-0 274 846 (ROSENBLUTH) * Column 8, line 57 - column 9, line 3 *	1,5	
A	EP-A-0 186 267 (OSBORNE)		

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 B
A 61 F
A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	28-03-1989	GLAS J.

CATEGORY OF CITED DOCUMENTS

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